**知情同意书修正说明书**

## Document Amendment History

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| --- | --- |
| **项目名称** |  |
| **审查编号** |  |
| **原版本号/日期**  **Old Version/Date:** |  |
| **修改后版本号/日期**  **New Version/Date:** |  |
| **所属层面**  **ICF Specification** | □**项目层面Master**  □**国家/区域层面Country/Region Specific**  □**中心层面 Site Specific** |
| **重新知情的范围**  **Revised ICF Distribution** | □**试验进行中的受试者 Subjects Ongoing**  □**完成试验的受试者 Subjects Completed Study**  □**提前终止试验的受试者 Subjects Early Discontinuation**  □**用药结束后随访的受试者 Subjects In Follow Up**  □**不适用 Not Applicable** |

| **主题**  **Subject** | **修订章节/页码**  **Section/Page** | **原文**  **Old text** | **修订后内容**  **New text** | **更改原因**  **Reason for change** |
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主要研究者签名： 日期：